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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/648,667 | 08/26/2003 | Chengjin M. Huang | AM101193 | 3920 |

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| EXAMINER | |
|---|---|
| LE, EMILY M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/648,667 | HUANG, CHENGJIN M. | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04/28/2006 and 06/28/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☒ Claim(s) *22* is/are allowed.

6)☒ Claim(s) *1-10 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/28/2006 has been entered.

### *Status of Claims*

2. Claims 1-22 are pending. Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-10 and 19-22 are under examination.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 and 19-21 require that the claimed antibody be specific for an epitope that is unique of inactivated FIV encoded glycoprotein. In the instant, the recitation "an epitope that is unique of inactivated FIV encoded glycoprotein" renders

the claims indefinite because it is not clear how the term "unique" contributes to the epitope of inactivated FIV encoded glycoprotein. For example, is the term "unique" directed at the a structural assembly that is different from inactivated and active FIV encoded glycoprotein, or does the term refers to a difference in amino acid sequence...etc. In the instant, it is not clear what is encompassed by the term "unique", i.e., what is it that renders an epitope "unique". Hence, the claims are rendered indefinite because of the recitation "unique".

The following is directed at claims 7 and 21: MPEP § 608.01(v) [R-2] provides: The expressions "trademarks" and "names used in trade" as used below have the following meanings: Names Used in Trade: a nonproprietary name by which an article or product is known and called among traders or workers in the art, although it may not be so known by the public, generally. Names used in trade do not point to the product of one producer, but they identify a single article or product irrespective of producer. Names used in trade are permissible in patent applications if: (A) Their meanings are established by an accompanying definition which is sufficiently precise and definite to be made a part of a claim, or (B) In this country, their meanings are well-known and satisfactorily defined in the literature. Condition (A) or (B) must be met at the time of filing of the complete application.

And MPEP § 608.01 (v) [R-2] (5$^{th}$ paragraph, section I) also provides the following: If proper identification of the product sold under a trademark, or a product referred to only by a name used in trade, is omitted from the specification and such identification is deemed necessary under the principles set forth above, the examiner

should hold the disclosure insufficient and reject on the ground of insufficient disclosure any claims based on the identification of the product merely by trademark or by the name used in trade.

The following rejection is directed at the monoclonal antibody product referred to as mAb 1D9. In the instant, the specification fails establish a sufficiently precise and definite meaning for the monoclonal antibody product. All that is provided in the specification is the following: mAb 1D9 is a monoclonal antibody that recognizes the surface protein component of the inactivated FIV, and not that of the live FIV, and that the heavy and light chains of said antibody is 50 Kd and 25 Kd. However, beside this one biological characteristics, and general characterization on the molecular weight of the heavy and light chains, the specification has not set forth any additional insight relating to the monoclonal antibody product known as mAb 1D9. In the instant, the specification has not set forth any additional guidance that would allow a sufficiently precise identification of the product known as mAb 1D9. The specification does not contain any structural data for mAb 1D9. The complete amino acid sequence of the product known as mAb 1D9 is not provided by the specification. Nor is the amino acid sequence for the complementarity determining regions of mAb 1D9 is provided. Hence, in the absence of a definition or guidance that would allow a sufficiently precise and definite identification of the product known as mAb 1D9, the claims are rendered indefinite.

5. Claims 1-6, 8-10 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a genus of monoclonal antibodies that is specific for an epitope unique to an inactivated feline immunodeficiency virus (FIV)-encoded glycoprotein, wherein the monoclonal antibody specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein.

To provide adequate written description and evidence of possession of **a claimed genus**, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings; or iii) disclosure of relevant identifying characteristics, such as disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, correlation between structure and function, and methods of making. The analysis is as follow:

**i) Sufficient description of a representative number of species by actual reduction to practice:** The specification only teaches of one monoclonal antibody, mAb 1D9, that is disclosed to specifically react with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. The specification does not teach of any other monoclonal antibodies beside mAb 1D9. Hence, the specification fails to provide sufficient description of a representative number of species by actual reduction to practice.

**ii) Sufficient description of a representative number of species by reduction to drawings:** The specification contains one drawing, Figure 1. Figure 1 sets forth the molecular weight of the heavy and light chain of mAb 1D9. No other antibodies is set forth in Figure 1. Hence, the drawing fails to provide a sufficient description of a representative number of species by reduction to drawings.

**iii) Sufficient description of a representative number of species by disclosure of relevant identifying characteristics:** The specification only teaches that mAb 1D9 specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. The specification does not forth neither the complete or partial structure of antibodies encompassed by the genus of antibodies instantly claimed. The specification does not set forth any structural requirements or guidance relating to the claimed antibodies and the specified functional characteristic, specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. All that is present is the asserted functional characteristics, specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. However, in the absence of any structural data that relates to the asserted functional characteristic, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of compounds based on the teaching from the specification.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). And therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only a monoclonal antibody identified as mAb 1D9, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-10 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically monoclonal antibodies, mAb 1D9. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. In the instant, while a method for making the antibodies, including of those identified as mAb 1D9 is provided in the specification, however, it is found that a deposit of such biological material is necessary for the specification fails to set forth any structural characteristics known to mAb 1D9. In the absence of any teachings pertaining to the structural characteristics of monoclonal antibodies identified as mAb 1D9, the skilled artisan would not be able to make monoclonal antibodies identified as mAb 1D9. Hence, the biological materials are not so obtainable in the absence of a deposit or additional guidance from the specification. In the instant, the requirements of 35 U.S.C § 112 may be satisfied by a deposit of biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. Applicant may make a deposit at an acceptable depository, which 37 CFR 1.803 provides as

(a) A deposit shall be recognized for the purposes of these regulations if made in:

(1) any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last requires or from the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replace if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however Applicant is cautioned to avoid the entry of new matter into the specification by addition any other information. Finally,

Applicant is advised that the address of the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor et al.[1]

The claims are directed at a hybridoma cell line.

O'Connor et al. teaches a hybridoma cell line that is suitable for obtaining monoclonal antibodies, specifically, monoclonal antibodies to feline immunodeficiency virus (FIV). [Lines 66, column 4 to line 56, column 5, in particular.]

The Office notes that the preamble of the claims require that the hybridoma cell line be that is suitable for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein. However, upon careful review of the preamble to determine if it recites structural limitation(s) or is merely a statement of purpose or use, it is found that the stated preamble is merely a statement of purpose or

[1] O'Connor et al., U.S. Patent No. 5177014, published January 05, 1993.

use. Hence, the claims remain to be directed to only a hybridoma cell line that can be used for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein. Thus, in the instant, O'Connor et al. teaches a hybridoma cell line. The hybridoma cell line of O'Connor could also used for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein. Hence, O'Connor et al. teaches the claimed invention. Thus, O'Connor et al. anticipates the claimed invention. For additional guidance relating to the effect of preambles, see MPEP § 2111.02 [R-3].

***Conclusion***

10. Claims 1-10 and 19-21 stand rejected. Claim 22 remains to be free of the art. Thus, should Applicant would like to proceed with the allowance of the subject matter encompassed by claim 22, Applicant should contact the Office, Examiner Emily Le, 571 272 0903.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily Le 9/06/06

Emily Le
Patent Examiner
Art Unit 1648